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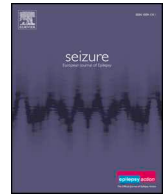
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EEG in fitness to drive evaluations in people with epilepsy — Considerable variations across Europe

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ABSTRACT

Purpose: Epilepsy patients consider driving issues to be one of their most serious concerns. Ideally, decisions regarding fitness to drive should be based upon thorough evaluations by specialists in epilepsy care. In 2009, an EU directive was published aiming to harmonize evaluation practices within European countries, but, despite these recommendations, whether all epileptologists use the same criteria is unclear. We therefore conducted this

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study to investigate routine practices on how epileptologists at European epilepsy centers evaluate fitness to drive.

Methods: A questionnaire was sent to 63 contact persons identified through the European Epi-Care and the Epilepsy network. The questionnaire addressed how fitness-to-drive evaluations were conducted, the involvement of different professionals, the use and interpretation of EEG, and opinions on existing regulations and guidelines.

Results: The questionnaire was completed by 35 participants (56 % response rate). Results showed considerable variation regarding test routines and the emphasis placed on the occurrence and extent of epileptiform discharges revealed by EEG. 82 % of the responders agreed that there was a need for more research on how to better evaluate fitness-to-drive in people with epilepsy, and 89 % agreed that regulations on fitness to drive evaluations should be internationally coordinated.

Conclusion: Our survey showed considerable variations among European epileptologists regarding use of EEG and how findings of EEG pathology should be assessed in fitness-to-drive evaluations. There is a clear need for more research on this issue and international guidelines on how such evaluations should be carried out would be of value.

1. Introduction

Several studies have indicated that active epilepsy is associated with an increased risk of motor vehicle accidents [1–6]. People with epilepsy (PWE) consider driving issues to be one of the concerns with the most impact on quality of life [1,7], and a balance needs to be achieved between society's need for traffic safety and patients' wish for autonomy and independence by being able to hold a driving license. In 2003, an "Epilepsy and driving working group" was established to harmonize regulations within the European Union (EU) regarding criteria for epilepsy patients being able to hold a Group 1 license (ordinary driving license for driving cars, motorcycles, and mopeds, not including taxis) and a Group 2 license (commercial or vocation driving license for large goods vehicles, lorries, passenger-carrying vehicles with 9 or more seats, also including taxis, and horse boxes). The recommendations of the working group for regulations for PWE holding these licenses were

implemented as an EU directive in 2009 with harmonization on the definition on epilepsy, periods of seizure freedom, and seizure types acceptable for the patient being declared fit to drive, see Table 1 [8]. Guidelines on when and how to conduct EEG, or how to evaluate interictal EEG pathology with respect to being fit to drive were not included, except that drivers with a group 2 license have to have a normal EEG.

Subsequently, national regulations followed the EU directive and other non-EU countries have, to varying extents, also adopted the regulations. The directive also states that EU member states are allowed to impose stricter standards than the minimum EU requirements. This flexibility regarding the implementation of internationally agreed standards provides the opportunity for variations in national regulations, including different approaches on how fitness-to-drive evaluations are performed in epilepsy centers across Europe. In the vast majority of EU and EEA countries a specialist (neurologist) or a general

Table 1

Summary over regulations from the Directive 2006/126/EC of the European Parliament and of the Council of 20 December 2006 on driving licenses with regard to epilepsy [8].

	Group 1: drivers of motorcycles and cars	Group 2: drivers of trailers and busses
Definitions	Epilepsy: two or more epileptic seizures, less than five years apart. A provoked epileptic seizure: seizure with a recognizable causative factor that is avoidable.	
General rules	Under license review until seizure-free for at least five years.	Should be without anti-epileptic medication for the required period of seizure freedom. No relevant cerebral pathology established and no epileptiform activity on the electroencephalogram (EEG).
Provoked epileptic seizure	Able to drive on an individual basis, subject to neurological opinion.	Able to drive on an individual basis, subject to neurological opinion.
First or single unprovoked seizure	Able to drive after a period of six months without seizures.	EEG and neurological assessment performed after the acute episode. A person with a structural intra-cerebral lesion who has increased risk of seizures should not be able to drive vehicles of group 2 until the epilepsy risk has fallen to at least 2 % per annum.
Other loss of consciousness	Should be assessed according to the risk of recurrence while driving.	Able to drive once five years' freedom from further seizures has been achieved without the aid of anti-epileptic drugs.
Epilepsy	Fit to drive after a one-year period free of further seizures.	Should be assessed according to the risk of recurrence while driving. The risk of recurrence should be 2 % per annum or less.
		Fit to drive after 10 years freedom from further seizures without the aid of anti-epileptic drugs. Possible exceptions: recognized good prognostic indicators or 'juvenile epilepsy'.
		Drivers with disorders with an increased risk of seizures, even if seizures have not yet occurred, should not be able to drive vehicles of group 2 until the epilepsy risk has fallen to at least 2 % per annum.
Seizures exclusively in sleep	Fit to drive so long as this pattern has been established for a period corresponding to the seizure-free period required for epilepsy.	
Seizures without influence on consciousness or the ability to act	Fit to drive so long as this pattern has been established for a period corresponding to the seizure-free period required for epilepsy.	
Seizures because of a physician-directed change or reduction of anti-epileptic therapy	Patient may be advised not to drive from the commencement of the period of withdrawal and thereafter for a period of six months after cessation of treatment. Seizures occurring during physician-advised change or withdrawal of medication require three months off driving if the previously effective treatment is reinstated.	

practitioner makes a statement concerning the patient's condition in relationship to obtain a driving license: The ultimate/formal authority to decide whether the person is allowed to drive or not lies with different authorities in the different countries.

Table 2

Main questions from survey with results on practices on conducting fitness-to-drive evaluations are done, n (%).

Have routines been established at your center for estimating the risk of seizures?	
Yes	11 (39.3 %)
No	17 (60.7 %)
Which seizure types would be acceptable for FTD in a patient being evaluated at your center? (MCP)	
No seizures at all	17 (60.7 %)
Sleep-related seizures	22 (78.8 %)
Focal seizures without impaired awareness and motor symptoms	19 (67.9 %)
Seizures starting with an aura evolving to any seizure type	2 (7.1 %)
Other ^a	5 (17.9 %)
How much impact does EEG has on your decision about the FTD? (OCP)	
None	1 (3.6 %)
Low	10 (35.7 %)
Medium	11 (39.3 %)
High	6 (21.4 %)
Which types of EEG are used? (MCP)	
No EEG	1 (3.5 %)
Standard EEG	20 (71.4 %)
Sleep-deprived EEG	10 (35.7 %)
24 h ambulatory EEG	4 (14.3 %)
12–24 h long-term video EEG	16 (57.1 %)
Which other test procedures are used? (MCP)	
Hyper-ventilation	24 (85.7 %)
Photoc stimulation	23 (82.1 %)
Clinical verbal testing during pathology	16 (57.1 %)
Reaction-time testing (RT)	12 (42.9 %)
Driving simulator	0
Other ^b	4 (14.3 %)
No testing during EEG	9 (32.1 %)
Which duration of generalized discharges (GD) in the EEG do you consider to be compatible with FTD? (OCP)	
No GD acceptable	4 (14.3 %)
Shorter than 1 s	2 (7.1 %)
Shorter than 2 s	2 (7.1 %)
Shorter than 3 s	6 (21.4 %)
Any GD without clinical symptoms	4 (14.3 %)
We use RT	4 (14.3 %)
No opinion	0
Other ^c	6 (21.4 %)
Which duration of focal discharges (FD) in the EEG do you consider to be compatible with FTD? (OCP)	
No FD acceptable	3 (10.7 %)
Shorter than 1 s	1 (3.6 %)
Shorter than 2 s	1 (3.6 %)
Shorter than 3 s	5 (17.9 %)
Any FD without clinical symptoms	9 (32.1 %)
We use RT	2 (7.1 %)
No opinion	1 (3.6 %)
Other ^c	6 (21.4 %)
How great an increase in reaction time due to epileptic discharges would be considered acceptable for FTD? (OCP)	
No increase acceptable	4 (14.3 %)
Maximum 100 ms	3 (10.7 %)
Maximum 300 ms	1 (3.6 %)
Maximum 500 ms	3 (10.7 %)
Maximum 1 s acceptable	2 (7.1 %)
No opinion	11 (39.3 %)
Other ^d	4 (14.3 %)

Table 2 (continued)

What is the maximum frequency of GD considered to be compatible with FTD? (OCP)	
1 pr minute	1 (3.6 %)
1 pr 15 min	5 (17.9 %)
1 pr hour	0
1 pr 4 h	4 (14.3 %)
1 pr day	0
No GD accepted	4 (14.3 %)
No opinion	14 (50 %)

FTD = fitness to drive, GD = generalized discharges, FD = focal discharges, RT = reaction time testing, MCP = multiple choice possible, OCP = only one choice possible.

^a “Subtle myoclonias” and “Reflex seizures where stimulus can be avoided”.

^b “Cognitive activation like Hanoi Tower”, “Psychological test batteries” and “Driving test with an expert”.

^c “Clinical testing”.

^d “We don't have rules for this” and “RT is compared to individual baseline testing without EEG discharges”.

The use of EEG data in the evaluations, in addition to consideration of the duration of the period of freedom from seizures, is not straightforward. Discharges of epileptiform activity in the EEG can have different durations and frequencies, and can also have different effects on cognition and responsiveness. Interpretations of these issues are left open for the neurologist to decide upon.

This study was performed in order to obtain insights in how fitness-to-drive evaluations are conducted by epileptologists at tertiary epilepsy centers across Europe, and to learn about how the challenges are handled in daily practice.

2. Methods

An online survey (suppl. data) was created using the Questback system (<http://www.questback.com>), and contact persons in the E-epilepsy and Epi-Care network in epilepsy centers in Europe were sent invitations by email with a link to the questionnaire. It was assumed that these contact persons represent the main opinions on these issues in their country, but the recipients could forward the survey to colleagues should they not personally have experience with fitness-to-drive evaluations. The invitations were first sent in December 2018, and reminders were sent to non-responders up to four times until February 2019.

If the answer to the first question as to whether the center was involved in fitness-to-drive issues was “No”, the survey was completed. If the answer was “Yes”, 49 further questions were introduced with the intention of obtaining information on practices on fitness-to-drive evaluations regarding Group 1 (ordinary) driving licenses. The questions were grouped as: (i) general characteristics of the center; (ii) routines in conducting fitness to drive evaluations; and (iii) opinions on the need for more regulations, guidelines, or research on these topics.

3. Results

Of the 63 contacts invited to participate in the survey, 35 (56 %) responded by answering the initial questions in the questionnaire. Of these, seven (20 %) answered that their centers were not involved in this issue for PWE; the other 28, representing 26 different epilepsy centers, answered that their centers were conducting such evaluations for PWE and answered all 49 subsequent questions in the questionnaire. Some of the main results from this questionnaire are summarized in Table 2.

3.1. General characteristics

Among the 28 participants completing the full questionnaire, 16 different European countries were represented from one to five centers,

with 22 of the participants based in countries within the EU (Croatia 1, Czech Republic 1, Finland 1, France 2, Germany 5, Greece 1, Hungary 3, Italy 1, Lithuania 1, Netherlands 1, Romania 2, Spain 1, Sweden 1, UK 1, and 6 from non-EU countries (Norway 2 and Switzerland 4).

All 28 of these participants reported that epileptologists were involved in conducting the fitness-to-drive evaluations at their centers. In addition, six (22 %) reported that neuropsychologists were involved in the evaluations, five (18 %) reported the involvement of clinical neurophysiologists, three (11 %) pediatricians, three (11 %) health personnel of other specialties, and one participant (4 %) reported that a general practitioner was involved in the evaluation.

In terms of how many evaluations were conducted, two participants (7 %) reported their centers conducted 1–10 evaluations annually, nine (32 %) reported 11–30 per year, three (11 %) reported 31–50 per year, five (18 %) reported 51–100 per year, and the remaining nine (32 %) reported that more than 100 such evaluations were conducted annually at their centers.

3.2. The role of EEG in fitness-to-drive evaluations

Among the 28 participants completing the full questionnaire, 11 (39 %) reported that their national guidelines required EEG in these evaluations, and 17 (61 %) reported that EEG results have a medium or high impact on the outcome of their evaluations.

Use of standard EEG was reported by 20 participants (72 %), and 16 (57 %) used 12–24 h video-EEG long-term monitoring. In addition, 24 (86 %) used photic stimulation and/or hyperventilation, 16 (57 %) used “clinical verbal testing”, and 12 (42 %) used reaction-time testing. Nine of the participants (32 %) did not use any kind of behavioral testing during EEG. None of the participants reported the use of a driving simulator integrated with EEG.

Regarding fitness-to-drive approval and the distribution and duration of interictal discharges, four (14 %) reported that they would not approve any PWE for a driving license should generalized discharges be registered in EEG, 2 (7 %) would approve PWE if the generalized discharges were shorter than 1 s, 2 (7 %) if shorter than 2 s, 6 (21 %) if shorter than three seconds and four (14 %) responded that they would accept longer generalized discharges, provided that there were no clinical symptoms. 4 (14 %) stated they used reaction time tests to decide and 6 (21 %) stated they used clinical testing to decide. Focal discharges were considered more acceptable than generalized discharges. Regarding the frequency of interictal discharges, 14 participants (50 %) had no opinion concerning generalized discharges, and 16 (57 %) had no opinion concerning focal discharges.

Regarding how large an increase in reaction time due to epileptic discharges would be considered acceptable, 11 participants (39 %) had no opinion, and four (14 %) accepted no increase in reaction time. In contrast, three participants (11 %) would accept increases of 100 milliseconds (ms), one (4 %) would accept increases of 300 ms, three (11 %) would accept 500 ms increases, and two (7 %) considered 1000 ms as the maximum acceptable increase in reaction time.

Table 3

Responses on opinions on research, guidelines, and regulations regarding fitness-to-drive evaluations, n (%).

	1 “Totally disagree”	2	3	4	5 “Totally agree”
“Regulations from the authorities are adequate for evaluating FTD in PWE.”	3 (10.7 %)	4 (14.3 %)	7 (25.0 %)	12 (42.9 %)	2 (7.1 %)
“Regulations from the authorities are sufficiently detailed for conducting a fair and objective evaluation of FTD in PWE”	3 (10.7 %)	8 (28.6 %)	7 (25 %)	5 (17.9 %)	5 (17.9 %)
“Regulations from the authorities on how to evaluate FTD in PWE should be more detailed”	4 (14.3 %)	4 (14.3 %)	7 (25 %)	2 (7.1 %)	11 (39.9 %)
“It is easy to evaluate pathological EEG findings in seizure-free patients with regard to FTD.”	4 (14.3 %)	7 (25 %)	6 (21.4 %)	6 (21.4 %)	5 (17.9 %)
“Regulations on evaluation of FTD in PWE should be internationally coordinated “	1 (3.6 %)	1 (3.6 %)	1 (3.6 %)	6 (21.4 %)	19 (67.9 %)
“There is a need for more research on how to evaluate FTD in PWE”	0 (0%)	3 (10.7 %)	2 (7.1 %)	6 (21.4 %)	17 (60.7 %)
“Recommendations have to be established for epilepsy patients who want to use vehicles with autonomous car technologies”	0 (0%)	1 (3.6 %)	3 (10.7 %)	6 (21.4 %)	18 (64.3 %)

FTD = fitness to drive. PWE = people with epilepsy.

3.3. Opinions on regulations and need of more research

The participants were asked to provide information regarding the extent to which they agreed with several statements regarding regulations and research on fitness-to-drive evaluations. The responses are summarized in Table 3.

The statement “Regulations from the authorities are adequate for evaluating fitness to drive in people with epilepsy” was agreed with by 14 participants (50 %) (Options 4 + 5 in Table 3), whereas 10 participants (36 %) agreed with the statement “Regulations from the authorities are sufficiently detailed for conducting a fair and objective evaluation of fitness to drive in PWE”. This small difference in opinion on fitness-to-drive evaluations became clearer with the responses to the next question, for which 13 participants (46 %) agreed that “Regulations from the authorities [...] should be more detailed”. In addition, 23 participants (82 %) agreed that there was a need for more research on how to better evaluate fitness-to-drive in people with epilepsy, and 25 (89 %) agreed that regulations on fitness to drive evaluations should be internationally coordinated. Furthermore, 24 participants (86 %) also agreed that there was a need for recommendations for PWE who want to use vehicles with autonomous car technologies.

4. Discussion

The results of this survey indicate differences between European epilepsy centers regarding fitness-to-drive evaluations of PWE.

Opinions regarding use of EEG examination in these evaluations and how generalized and focal discharges without clinical symptoms should be considered for the fitness to drive varied greatly. These differences indicate a considerable lack of consensus on how fitness to drive evaluations should best be conducted, which may reflect the lack of evidence-based guidelines.

Several publications have reported on the effect of epileptiform discharges on cognition. Browne et al. [9] showed in 1974 that even during short general discharges of under 1 s, and without observable seizure symptoms, most patients stopped completely in their continuous motor-performance task. However, EEG discharges of similar appearance can be associated with impaired responsiveness in some patients, but have no discernible impact in others [10]. Despite PWE responding appropriately during generalized discharges, reaction times can be considerably delayed [11,12] and could contribute to relevant and observable lateral drifts of vehicles in real traffic [13]. To the authors’ knowledge, use of the results from these studies in establishing guidelines on how to use EEG in fitness-to-drive evaluations has not been attempted.

Although PWE may consider themselves seizure free, these studies raise the question regarding the extent to which the patients can be considered genuinely free of seizures, as it is open to debate how long a cognitive impairment due to epileptiform discharges can last before it should be defined as a short absence or dyscognitive seizure [14].

It can also be discussed if the frequency of such episodes should be a

separate factor when conducting risk assessments and fitness-to-drive evaluations.

4.1. Limitations of study

The 28 participants who completed the survey are only a small fraction of all the epileptologists conducting fitness-to-drive evaluations in Europe, and this may limit the validity of the survey. However, the high number of evaluations performed at the centers associated with the participants in the survey indicates that they have considerable experience with such evaluations. We therefore assume that the results can be considered indicative of the major opinions of these issues in tertiary epilepsy centers in Europe.

5. Conclusion

Our survey showed considerable variations among European epileptologists regarding use of EEG and how findings of EEG pathology should be assessed in fitness-to-drive evaluations. There is also little agreement between centers on the significance of prolonged reaction times during epileptiform discharges and fitness to drive.

Most of the participants who completed the questionnaire agreed that there was a need for more research and international guidelines on how to conduct evaluations of fitness to drive in PWE. This widespread opinion strongly supports the need for further research in this field.

Disclosures/conflict of interest

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